GE HealthCare

New indication

Now approved for use in pediatric patients

OPTISON ON YOUR SIDE

Safety
Simplicity
Image quality

in every vial

OPTISON™
(Perflutren Protein-Type A Microspheres Injectable Suspension, USP)

The ONLY Polyethylene Glycol (PEG) free ultrasound enhancing agent (UEA) in the US

IMPORTANT SAFETY INFORMATION ABOUT OPTISON

WARNING: SERIOUS CARDIOPULMONARY REACTIONS

Serious cardiopulmonary reactions, including fatalities, have occurred uncommonly during or following perflutren-containing microsphere administration. Most serious reactions occur within 30 minutes of administration.

- Assess all patients for the presence of any condition that precludes OPTISON administration
- Always have resuscitation equipment and trained personnel readily available

Please see Important Safety Information about Optison on the back of this brochure, and a QR code to the full Prescribing Information.

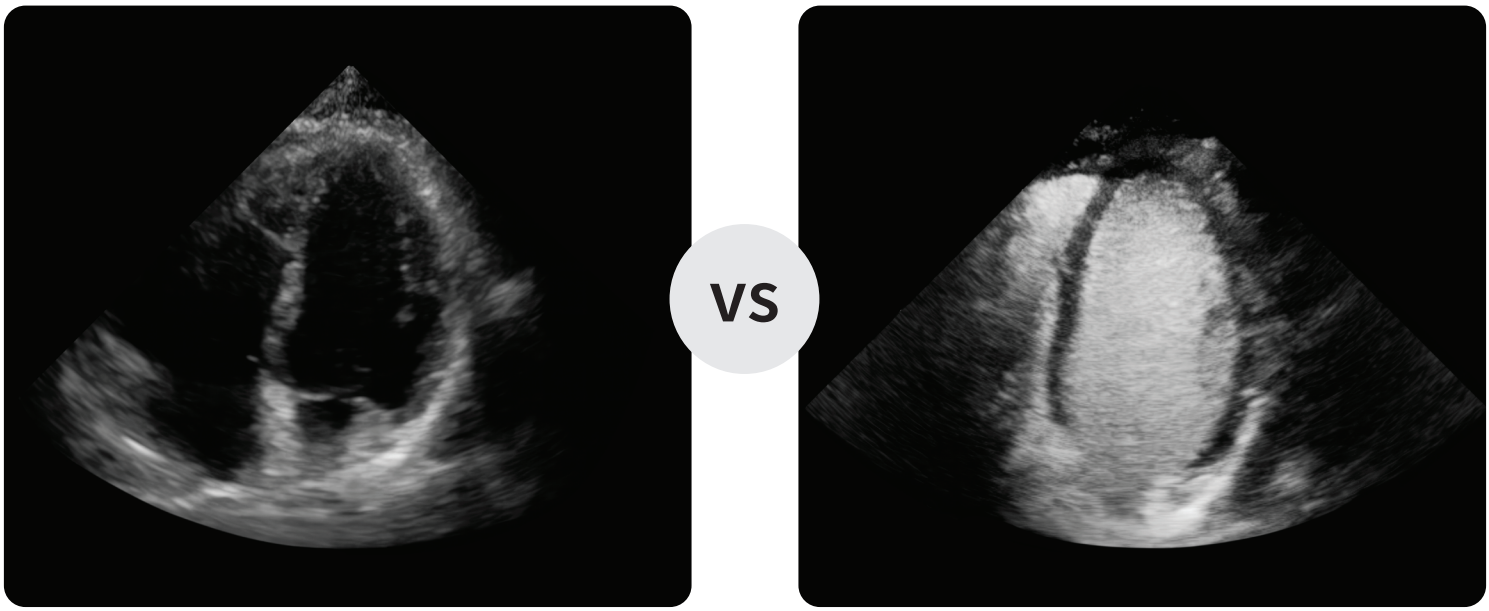
Optison helps you see the light

Clear ultrasound images can be the difference between days, sometimes weeks, of additional testing.
Approximately 10 to 15% of resting[1] echocardiograms yield suboptimal images.
By using a UEA, 75 to 90% of previously suboptimal echocardiograms[2] can be improved.

Optison is the **ONLY PEG-free** UEA that can help enhance visualization of the left ventricle in suboptimal echocardiograms.[2] Optison offers improved image quality that can aid diagnosis, giving patients the clarity and peace of mind they deserve.

Count on Optison for a brighter, clearer future in patient care

Clear delineation of the endocardial borders may help facilitate evaluation of LV wall motion and function



Unenhanced TTE | **Optison-enhanced TTE[a,b]**

[a]Images obtained with VividTM S70 scanner using Optison.

[b]Optison and Vivid™ S70 scanner are NOT Combination Products as classified under 21 CFR 3.2(e). Both Drug & Device were approved/cleared independent of the other by the FDA. While the products can be used in conjunction with each other, Drug does not require the use of this specific Device, nor does Device require the use of this specific Drug.

IMPORTANT SAFETY INFORMATION ABOUT OPTISON

WARNING: SERIOUS CARDIOPULMONARY REACTIONS

Serious cardiopulmonary reactions, including fatalities, have occurred uncommonly during or following perflutren-containing microsphere administration. Most serious reactions occur within 30 minutes of administration.

- **Assess all patients for the presence of any condition that precludes OPTISON administration**
- **Always have resuscitation equipment and trained personnel readily available**

Please see Important Safety Information about Optison on the back of this brochure, and a QR code to the full Prescribing Information.

Your UEA of choice

Safety first

Optison's well-established safety profile is supported by post-marketing studies across multiple care settings[3-5]

ONLY PEG-free UEA in the US

FDA has never classified Optison as a blood product

The microsphere shell consists of albumin, a natural protein[6]

The adverse events for UEAs including Optison are reported quarterly in the FAERS* database since it first went to market[7]

***FAERS data cannot be used to calculate the incidence of an AE or medication error in the U.S. population. The FAERS data by themselves are not an indicator of the safety profile of the drug. Duplicate and incomplete reports are in the system. Existence of a report does not establish causation. Information in the reports has not been verified. Rates of occurrence cannot be established with reports.**

Improves workflow efficiency

Optison can integrate seamlessly into your workflow, with less than 60 seconds from suspension to injection[8]

On-The-Go
No shaker and no activation required

Quick & Easy
From suspension to injection[8]

24 hrs

Convenient
Portable and stable at room temperature for up to 24 hours

Diagnostic confidence

Optison can enhance the diagnostic value of echocardiography in technically difficult studies[9]

97%

of scans become assessable with Optison enhancement, vs 31% (before Optison enhancement)

90%

of patients that required additional testing before enhancement no longer needed it

71%

of patients with an LVEF<30 had a change in treatment plan in medical therapy and/or procedure

Impact of Optison on the assessment of regional wall motion (N=176 patients)[9]

GE HealthCare

Ordering information

Optison is provided in 3 mL vials and is available in two package quantities, 5 or 18, respectively. Spikes for venting Optison prior to withdrawal by syringe are also available.

	Optison 3 mL - **5 VIALS**	Optison 3 mL - **18 VIALS**	**Optispikes**
SKU	1173653	1182095	1186905
Order size	Packs of 5	Packs of 18	Packs of 20
NDC #	00407-2707-03	00407-2707-18	00000-2710-21

IMPORTANT SAFETY INFORMATION ABOUT OPTISON

INDICATIONS: OPTISON is an ultrasound contrast agent indicated for use in adult and pediatric patients with suboptimal echocardiogram to opacify to the left ventricle to improve the delineation of the left ventricle endocardial borders.

WARNING: SERIOUS CARDIOPULMONARY REACTIONS

Serious cardiopulmonary reactions, including fatalities, have occurred uncommonly during or following perflutren-containing microsphere administration. Most serious reactions occur within 30 minutes of administration

- Assess all patients for the presence of any condition that precludes OPTISON administration
- Always have resuscitation equipment and trained personnel readily available

CONTRAINDICATIONS: OPTISON is contraindicated in patients with known or suspected hypersensitivity to perflutren or albumin.

WARNINGS AND PRECAUTIONS:

- Serious cardiopulmonary reactions including fatalities have occurred uncommonly during or shortly following perflutren-containing microsphere administration, typically within 30 minutes of administration. The risk for these reactions may be increased among patients with unstable cardiopulmonary conditions (acute myocardial infarction, acute coronary artery syndromes, worsening or unstable congestive heart failure, or serious ventricular arrhythmias).
- Serious anaphylactic reactions have been observed during or shortly following perflutren-containing microsphere administration, including shock, hypersensitivity, bronchospasm, throat tightness, angioedema, edema (pharyngeal, palatal, mouth, peripheral, localized), swelling (face, eye, lip, tongue, upper airway), facial hypoesthesia, rash, urticaria, pruritus, flushing, and erythema have occurred in patients with no prior exposure to perflutren-containing microsphere products.
- When administering OPTISON to patients with a cardiac shunt, microspheres can bypass filtering of the lungs and enter the arterial circulation. Assess patients with shunts for embolic phenomena following OPTISON administration. OPTISON is only for intravenous administration; do not administer OPTISON by intra-arterial injection.
- High ultrasound mechanical index values may cause microsphere rupture and lead to ventricular arrhythmias. Additionally, end-systolic triggering with high mechanical indices has been reported to cause ventricular arrhythmias. OPTISON is not recommended for use at mechanical indices greater than 0.8.

Adverse reactions

Common adverse reactions (incidence ≥ 0.5%) were: headache, nausea and/or vomiting, warm sensation or flushing, dizziness, dysgeusia, chills or fever, flu-like symptoms, malaise/weakness/fatigue, chest pain, dyspnea, injection site discomfort, and erythema. Cardiac arrests and other serious but nonfatal adverse reactions were uncommonly reported in post-approval use. Reports also identified neurologic reactions (loss of consciousness or convulsions) as well as anaphylactoid reactions. Overall, the safety profile observed in pediatric patients from the clinical study was consistent with the safety profile in adult patients.

Use in specific populations

Pregnancy and lactation

There are no data with OPTISON use in pregnant woman to inform any drug-associated risks.

There are no data on the presence of perflutren protein-type A microspheres in human milk, the effects on the breastfed infant or the effects on milk production.

Pediatric Use

Safety and efficacy of OPTISON in pediatric patient is supported by evidence from adequate and well-controlled studies in adults and additional efficacy and safety data from a clinical study in 37 pediatric patients aged 9-17 years.

Geriatric Use

No overall differences in safety or effectiveness were observed in patients 65 years and over but a greater sensitivity to OPTISON in older individuals cannot be ruled out.

Please scan the QR code to see the full Prescribing Information, including Boxed Warning for additional important safety information.

To report SUSPECTED ADVERSE REACTIONS, contact GE HealthCare at 800 654 0118 (option 2 then option 1) or by email at GPV.drugsafety@gehealthcare.com or FDA at 800 FDA 1088 or www.fda.gov/medwatch

If you have questions regarding Optison, please refer to the below resources for assistance:

Customer Service
To place an order, call 800 292 8514

Medical Affairs
800 654 0118 (option 2, then option 3) or
medical.affairs@gehealthcare.com

Reimbursement Hotline
For reimbursement-related questions (eg, appropriate coding), call 800 767 6664

gehealthcare.com

OPTISON™
(Perflutren Protein-Type A Microspheres Injectable Suspension, USP)

May 2025 JB11443US

1. Senior R, Dwivedi G, Hayat S, Keng Lim T. Clinical benefits of contrast-enhanced echocardiography during rest and stress examinations. *Eur J Echocardiogr*. 2005;6(Suppl.2):S6-S13.
2. Mulvagh SL, Rakowski H, Vannan MA, et al. American Society of Echocardiography Consensus Statement on the Clinical Applications of Ultrasonic Contrast Agents in Echocardiography. *J Am Soc Echocardiogr*. 2008;21:1179-1201.
3. Reilly JP, Tunick PA, Timmermans RJ, et al. Contrast Echocardiography Clarifies Uninterpretable Wall Motion in intensive Care Unit Patients. *J Am Coll Cardiol*. 2000;35(2):485-490.
4. Exuzides A, Main ML, Colby C, Grayburn PA, Feinstein SB, Goldman JH. A retrospective comparison of mortality in critically ill hospitalized patients undergoing echocardiography with and without an ultrasound contrast agent. *J Am Coll Cardiol Img*. 2010;3:578-585.
5. Main M, Grayburn P, Lang R, et al. Effect of Optison on pulmonary artery systolic pressure and pulmonary vascular resistance. *Am J Cardiol*. 2013;112(10):1657-1661.
6. Levitt DG and Levitt MD. *Int J Gen Med*. 2016;9:229-255.
7. FAERS data cannot be used to calculate the incidence of an AE or medication error in the U.S. population. The FAERS data by themselves are not an indicator of the safety profile of the drug. Duplicate and incomplete reports are in the system. Existence of a report does not establish causation. Information in the reports has not been verified. Rates of occurrence cannot be established with reports.
8. Optison Prescribing Information. Marlborough, MA: GE HealthCare, 2021.
9. Zhao H, O'Quinn R, Ambrose, et al. Contrast-Enhanced Echocardiography Has the Greatest Impact in Patients With Reduced Ejection Fractions. *J Am Soc Echocardiogr*. 2018; 31(3):289-296.